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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,661	09/06/2006	Andrew Michael Lindsay Lever	6947-73323-01	3959

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EXAMINER	
MARVICH, MARIA	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
08/31/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/567,661	LEVER ET AL.	
	Examiner	Art Unit	
	MARIA B. MARVICH	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/17/10*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49 and 50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to an amendment filed 11/19/09. Claim 49 and 50 are pending.

Claim Objections

Claims 49 and 50 are objected to because of the following informalities: Claim 49 requires a number of minor amendments.

Claim 49 is directed to a method of delivering a therapeutic or antigenic protein or peptide to an individual. However, the claim does not subsequently refer to this protein or peptide. Secondly, the coding sequences should be operably linked to expression control sequences. Thirdly, articles are required prior to "antigenic protein" in line 1, "host cell" and pharmaceutical composition in line 4 and the article "the" prior to "heterologous nucleic acid" in line 7. Fifth, the recitation that the individual can be administered the virus, a vector system or host cell thereof is incongruent with the inclusion of the method of production of the virus. As the virus is produced b administering the vector system to the host cell comprising packaging sequences, neither of these can also be administered to the subject. Finally, the recitation "said vector being packaged" does not indicate how this step happens.

Overall, the claim should be amended such,

"A method of delivering a therapeutic or an antigenic protein or peptide to an individual comprising: administering to the individual an effective amount of a chimaeric virus comprising a heterologous nucleic acid sequence encoding the therapeutic or the antigenic protein or peptide wherein the nucleic acid sequence is under control of an expression control sequences, ~~of a~~

~~vector system, a host cell,~~ or a pharmaceutical composition ~~comprising said chimaeric virus~~ thereof, wherein the chimaeric virus is produced by a method comprising culturing a host cell which comprises one or more Simian Immunodeficiency Virus (SIV) nucleic acid sequences encoding ~~capable of producing~~ an SIV capsid wherein the SIV nucleic acid sequences are under control of expression control sequences and which further comprises a vector comprising a Human Immunodeficiency Virus type 2 (HIV-2) packaging signal and ~~a~~ the heterologous nucleic acid sequence; wherein said culturing results in said vector being packaged in the SIV capsid to produce the chimaeric virus."

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 49 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen et al (US 20060067948; see entire document). **This rejection is maintained for reasons of record in the office action mailed 3/17/10.**

Allen et al teach methods of making a virus wherein the method utilizes a vector comprising an HIV-2 packaging signal and a heterologous nucleic acid and sequences encoding an SIV envelope (see e.g. ¶ 0050, 0054 and 0059). The heterologous gene encodes a variety of

therapeutic proteins or peptides (see e.g. ¶ 0072). The virus is administered to humans for example (see e.g. ¶ 0076).

Response to Amendment

Applicants have argued that Allen et al by teachings methods of pseudotyping a vector comprising an HIV-1 packaging sequence do not anticipate the instant claims as the instant claims are drawn to an SIV capsid which requires more than the envelope gene product. These arguments are not persuasive for the following reasons. First, it is understood in the art that viral vectors are encapsulated within envelope proteins. And while other proteins can be part of the capsid, envelope protein which is responsible for pseudotyping establishes the nature of the capsid. For example, Allen et al describe such encapsulation,

> [0041] Preferably the packaging sequences present in such a vector correspond to those described above which are mutated to produce a packaging defective HIV-2 vector. Preferably a substantial portion of the packaging signal is included. In a preferred aspect, the packaging sequence comprises the sequence of SEQ ID NO: 1, or a fragment thereof or a variant thereof. A variant thereof may be identified as set out above in determining a region of the genome to be deleted. All of the sequences described above for mutation or deletion to produce an HIV-2 packaging defective vector are preferred sequences for incorporation into a vector such that the vector can be packaged by an HIV-2 capsid or protein envelope. In a preferred aspect, the packaging sequence is selected to allow the formation of a palindromic terminus, having the structure as shown in FIG. 1.

To this end, Allen et al teach a chimeric virus enveloped in an SIV envelope,

Applicants' arguments invoke limitations that are not part of the claims. Rather and as supported by the specification the chimeric virus comprises an SIV capsid,

> "[0058] The vectors comprising HIV-2 packaging sequences may be packaged, as described herein, by the SIV envelope or heterologous viral envelopes such as the Amphotrophic Murine Leukaemia Virus envelope, Vesicular Stomatitis Virus G protein

> (VSV-G) or other Rhabdovirus envelopes. These vectors may be capable of being packaged by HIV-1 and/or HIV-2."

Furthermore, the instant claims encompass such a situation by reciting that the host cell comprising "**one** or more Simian Immunodeficiency Virus (SIV) nucleic acid sequences". To this end, Allen et al express an SIV nucleic acid sequence "env" which is capable of forming a capsid in that it forms the envelope of the capsid. See for example ¶ 0054,

> " [0054] Retroviruses can in some cases be pseudotyped with the envelope glycoproteins of other viruses. Consequently, one can prepare a vector containing a sufficient number of nucleotides to correspond to an env gene from a different retrovirus. Preferably, the 5'LTR of this vector would be of the same genome as the env gene. Such a vector could be used instead of an HIV-2 env packaging-defective vector, to create virions. By such a change, the resultant vector systems could be used in a wider host range or could be restricted to a smaller host range. Using a vesicular stomatitis virus or rabies virus envelope protein would make the vector tropic for many different cell types."

Hence, by pseudotyped virus, the virus is enveloped or otherwise variantly within a capsid of a heterologous virus. Applicants also argue that the passages relate to attenuated viruses. However, to the contrary, Allen describes a number of uses of such viruses one of which is an attenuated virus (¶0059) . However, Allen et al are not limited to vectors that are attenuated. Rather, the invention of Allen et al is as a whole drawn to HIV2 packaging sequences that can be packaged in heterologous viral envelopes (see e.g. ¶ 0039) wherein the vector further comprises heterologous genes packaging into the HIV-2 genome through the use of the HIV-2 packaging sequences (see e.g. ¶ 0040). These heterologous genes can be therapeutic or immunogenic.

A broad interpretation of a claim by USPTO personnel will reduce the possibility that the claim, when issued, will be interpreted more broadly than is justified or intended. An applicant

can always amend a claim during prosecution to better reflect the intended scope of the claim." MPEP 2105. As set forth above in the claim interpretation, the claim language is so broad as to encompass the cited art. Specifically, applicants argue that the SIV protein of Allen et al does not have any function in the recognition of the HIV-2 RNA by the HIV-2 gag protein and that Allen et al do not include any SIV proteins that are involved in forming the intact core of the vector particle such as gag to recognize and capture the nucleic acid that goes into the center of the particle. By these arguments, applicants invoke properties that are not required of the claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD
Primary Examiner
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